

REMARKS

1. The Examiner's Objections to the Specification and Rejections of Claims 14-20 under 35 U.S.C. § 112, First Paragraph.

1.1 The Examiner has objected to the specification under 35 U.S.C. § 112, first paragraph, as failing to set forth an enabling disclosure and has rejected Claims 14-20 for the reasons set forth in the objection to the specification. In particular, the Examiner objects to the specification in that it purportedly fails to properly set forth clear enablement for aggregates containing mixtures of both algal types: *Thraustochytrium* and *Schizochytrium*. It is unclear to the Examiner whether the aggregates are made up of both algal types or only one type since the examples teach results for *Thraustochytrium* and not *Schizochytrium*.

Applicant respectfully traverses the Examiner's foregoing objection to the specification and the rejection of Claims 14-20 under 35 U.S.C. § 112 on the basis that the specification is not enabling for aggregates comprising mixtures of the algal types *Thraustochytrium* and *Schizochytrium*. In particular, Applicant submits that the text of the specification at page 3, lines 5-10, page 3, lines 26-28 through page 4, lines 1-2, page 4, lines 9-19, page 9, lines 14-18, page 12, lines 6-10, page 15, lines 17-22, page 16, lines 17-21, clearly supports the claims as currently drawn, i.e., that the cell aggregates can comprise *Thraustochytrium* and *Schizochytrium* and mixtures thereof. Moreover, there is no reason to expect that processes disclosed in the specification to enable one to produce the claimed biomass comprising one type of

organism would not work for producing a mixture of both types of organisms. Further, *Thraustochytrium* and *Schizochytrium* can be independently produced and mixed together to form a biomass comprising a mixture of the two types of organisms. It is well-settled that in the absence of a scientific or technical reason provided by the Examiner to doubt that a statement made by an applicant is true, the Patent Office is required to accept the statement as true. Moreover, it would be improper for the Examiner to interpret the examples in the application as limiting of the claims. Accordingly, Applicant respectfully submits that the specification is enabling for the use of mixtures of both algal types and requests the Examiner withdraw the objection to the specification and the rejection of Claims 14-20 under 35 U.S.C. § 112.

1.2 The Examiner has also rejected Claims 14-20 under 35 U.S.C. § 112 on the basis that the disclosure is enabling only for claims limited to a non-chloride containing sodium salt media used to produce the claimed microfloral biomass, and the specific set of culturing conditions utilized and exemplified in the specification. The Examiner further states that the specification is only enabling for the specific strains of *Thraustochytrium* and *Schizochytrium*, and that it would be burdensome to test all species and strains of the two genera claimed since well-defined parameters have not been set forth in the claims.

Applicant respectfully traverses the Examiner's rejection of Claims 14-20 under 35 U.S.C. § 112 on the basis that the disclosure

is only enabling for claims limited to the specific culturing conditions, including use of non-chloride-containing sodium salts. First, Applicant points out that Claims 14-20 are directed to a product, namely a microfloral biomass having certain characteristics, and have not been drafted in process format. The Examiner is apparently suggesting that the Applicant restructure its claims to product-by-process format to include recitations as to how the claimed product is obtained. Applicant, however, submits that Claims 14-20 are adequately enabled by the specification and Applicant has provided sufficient information to allow one of skill in the art to reproduce the claimed invention without undue experimentation. Applicant respectfully submits that it is not required to recite in product claims any and all processes by which that product can be made. Applicant notes that product-by-process claims are conventionally used when the product made by a particular process cannot be adequately characterized other than by describing the process by which it was made. In this instance, however, the microfloral biomass product can be and is well characterized without having to resort to a product-by-process format. Accordingly, Applicant respectfully submits that the disclosure is enabling for the claims as currently drawn, and furthermore, that it is improper for the Examiner to require Applicant to include process steps in its product claim.

Applicant also traverses the rejection by the Examiner based on the reasoning that the specification is only enabling for specific strains of *Thraustochytrium* and *Schizochytrium*. Applicant

respectfully submits that there are numerous strains of *Thraustochytrium* and *Schizochytrium* which are capable of being cultured to obtain the claimed invention. In this regard, the specification contains disclosures on page 8, lines 20-28 through page 9, lines 1-13, for methods for screening microorganisms of the genera *Thraustochytrium* and *Schizochytrium* to obtain strains of microflora which can be used to obtain the claimed invention. Accordingly, Applicant submits that the recitations in the claims are enabled by the breadth of the disclosures in the specification and requests the Examiner withdraw the rejection of Claims 14-20 under 35 U.S.C. § 112.

2. The Examiner's Rejection of Claims 14-20 under 35 U.S.C. § 101.

The Examiner has rejected Claims 14-20 under 35 U.S.C. § 101 because the claimed invention appears to be drawn to non-statutory subject matter. In particular, the Examiner states that the instant claims appear to be directed to an organism which has not been purified from nature. The Examiner has suggested to include the language "biologically pure" in the claims in order to distinguish the subject matter.

Applicant respectfully traverses the Examiner's rejection of Claims 14-20 under 35 U.S.C. § 101. In particular, Applicant submits that Claim 14 is drawn to a microfloral biomass comprising *Thraustochytrium*, *Schizochytrium* and mixtures thereof, having a cell aggregate size less than about 150 microns. A microfloral

biomass having these characteristics is not believed to exist in nature and therefore, the claimed microfloral biomass is not considered to be a product of nature, but rather, a product produced by humans using the specific processing techniques described in the application. Moreover, the Examiner has not cited any reference or provided any rationale to indicate that microfloral biomasses with the claimed characteristics exist in nature. Thus, Applicant submits that the inclusion of the language "biologically pure" in the claims is not required to distinguish the claimed subject matter because the claim language defines a non-naturally occurring biomass. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of Claims 14-20 under 35 U.S.C. § 101.

3. The Examiner's Rejection of Claims 14-20 under 35 U.S.C. 112, Second Paragraph.

3.1 The Examiner has rejected Claims 14-20 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner states that Claims 14, 19 and 20 are rendered vague and indefinite for the recitation of "less than about" because when "about" is used with "less than" the claims are confusing. Further, the Examiner has suggested to amend the claim language to include the recitation --in diameter-- in order to be consistent

with the description of the claimed cell aggregates on page 3, lines 20-25 of the specification.

Applicant respectfully traverses the Examiner's rejection of Claims 14, 19 and 20 as being vague and indefinite for the recitation of "less than about". Contrary to the Examiner's argument, the term "about" is not confusing when used with the phrase "less than". Applicant submits that the term "about" modifies the number "150", and not the phrase "less than". In other words, the phrase "less than about 150 microns" should be read to mean less than the value indicated by the phrase "about 150 microns". With regard to the suggestion by the Examiner to amend Claims 14, 19 and 20, Applicant has amended the claim language to read "in diameter" as the Examiner has suggested. For the foregoing reasons, Applicant respectfully requests the Examiner withdraw the rejection of Claims 14, 19 and 20 under 35 U.S.C. § 112, second paragraph as being indefinite.

3.2 The Examiner also states that Claim 16 is rendered vague and indefinite for the recitation of "and" on lines 4-5 of the claim, and because it is unclear if "an organism" is of a biologically pure organism. Also, the Examiner states that the language "and mutants thereof" is vague and suggests that Applicant delete such language and insert in its place --and mutant strains derived therefrom--. Further, the Examiner suggests that the language "wherein said mutants" should be replaced with --wherein said *Thraustochytrium*, *Schizochytrium* and mixtures thereof--.

With regard to the Examiner's rejection of Claim 16, Applicant has deleted the term "and" to correct an error made in the preliminary amendment when the language "mutant strains derived therefrom" was added to the claim. Applicant has also amended line 6 of Claim 16 to delete the term "mutants", and have inserted the phrase "*Thraustochytrium*, *Schizochytrium* and mixtures thereof" as suggested by the Examiner. Lastly, in response to the Examiner's rejection regarding Applicant's use of the term "an organism", Applicant has amended Claim 16 to recite instead "a microorganism". Applicant respectfully submits that the term "a microorganism" in Claim 16 is definite because in the context of the referenced sentence structure, the term "a microorganism" can only refer to "ATCC Nos. 20888 and 20889". Accordingly, Applicant respectfully submits that the language of Claim 16 is definite and particularly points out and distinctly claims the subject matter which Applicant regards as the invention and requests the Examiner withdraw the rejection of Claim 16 under 35 U.S.C. § 112, second paragraph.

3.3 With regard to Claim 18, the Examiner states that the claim is rendered vague and indefinite because it lacks an antecedent basis for the recitation of "wherein *Thraustochytrium* and *Schizochytrium*". The Examiner suggests that Applicant insert --said-- before [sic] the term "wherein" in the claim. Furthermore, the Examiner has suggested inserting --*Thraustochytrium*, *Schizochytrium* and mixtures thereof-- in the claim in order to clarify that "and mixtures thereof" would also have at least about 15% of the total sterol content.

With regard to the Examiner's rejection of Claim 18 under 35 U.S.C. § 112, second paragraph, as being vague and indefinite, Applicant has amended the claim as suggested by the Examiner to include "said" after the term "wherein", and has included the recitation "and mixtures thereof" in order to clarify that mixtures thereof would also have at least about 15% of the total sterol content. Accordingly, Applicant respectfully requests the Examiner withdraw the rejection of Claim 18 under 35 U.S.C. § 112, second paragraph as being indefinite.

4. The Examiner's Rejection of Claims 14-20 under 35 U.S.C. § 103.

The Examiner has rejected Claims 14-20 under 35 U.S.C. § 103 as being unpatentable over Kendrick et al. in view of Bajpal et al., and if necessary in further view of World Patent 89/00606. The Examiner states that although the claimed subject matter differs from the disclosure of Kendrick et al. in that a specific cell aggregate size less than about 150 microns is not specifically disclosed, it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to combine the teaching of Bajpal et al. with that of Kendrick et al. in order to optimize conditions for exposing the claimed algal cultures to light for growth and thus, produce a microfloral biomass having a cell aggregate size less than 150 microns. Moreover, the Examiner states that a microfloral biomass comprising two algal cultures

would have been expected to provide an omega-3 HUFA content of at least 0.5% dry weight in light of the teachings of WO 89/00606.

The Examiner further states that Claims 14-20 are rejected under 35 U.S.C. § 103 as being unpatentable over a combination of Bajpal in view of World Patent 89/00606. The Examiner states that although the claimed subject matter differs from the disclosure of Bajpal in that *Schizochytrium* is not specifically taught in the cited reference, it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to culture both *Thraustochytrium* and *Schizochytrium* and mixtures thereof to obtain a biomass having high fatty acid content.

The Applicant respectfully traverses the Examiner's rejection of Claims 14-20 under 35 U.S.C. § 103. While the Examiner has identified a basis in the combined references to serve as a motivation for those skilled in the art to desire organisms having a small cell aggregate size, the combined references do not, alone or in combination, teach or suggest how a small cell aggregate size can be obtained, as is taught in the present application. Moreover, Applicants submit that the basis identified by the Examiner was arrived at by use of a hindsight analysis using the benefit of Applicant's disclosure to guide in the combination of references.

The crux of the Examiner's argument is that one of ordinary skill in the art would combine the teachings of Kendrick et al. with Bajpal et al. (with WO 89/00606) or Bajpal et al. with WO 89/00606 and would desire and know how to obtain a microfloral

biomass having a cell aggregate size of less than about 150 microns to optimize exposure of the microorganisms to light to increase growth. This reasoning is not, however, supported by the teachings of Kendrick et al., Bajpal et al. or WO 89/00606, or any combinations thereof.

Initially, even if one assumes that the recognition of Bajpal et al. that higher access to light would teach that it is a desirous goal to have small cell aggregate sizes, Applicant submits that neither Bajpal et al. or other references of record provide any suggestion on how to accomplish that goal as is disclosed in the present application.

Moreover, it is noted that Kendrick et al. teach on page 19, column 2, lines 51-53 that any organism chosen for commercial production of a given polyunsaturated fatty acid would ideally be both oleaginous and produce a triacylglycerol oil rich in the desired fatty acid, and that none of the fungi Kendrick et al. examined, including those tested from the genera *Thraustochytrium* and *Schizochytrium*, fit these criteria. Accordingly, Kendrick et al. seemingly teach away from the use of microorganisms of the genera *Thraustochytrium* and *Schizochytrium* for use in commercial production of highly unsaturated fatty acids. Accordingly, there is no suggestion in Kendrick et al. which would lead one of skill in the art to combine it with the teachings of Bajpal et al.

With further regard to the Examiner's reasoning, Applicant submits that World Patent 89/00606 teaches nothing further from what is already recognized in Bajpal et al. on page 512, lines 31-

33, namely, that growth of *Thraustochytrids* can be stimulated through the use of light.

Applicant further submits that the Examiner has improperly used hindsight analysis in determining that the claims are obvious in light of the cited references. In contrast to the reasoning put forth by the Examiner, the Applicant submits that the claimed invention, and its utility were the result of a surprising discovery. For example, the Applicant discloses at page 10 lines 26-28 through page 11, line 3 in the specification that it has been surprisingly found that fermentation of the strains in the presence of a non-chloride containing sodium salt limits the cell aggregate size of the strains to less than about 150 microns, and further, at page 13, lines 25-28 through page 14, line 2, that such aggregates are useful as a food source for marine life unable to consume food particles larger in size. The Examiner, however, has used the Applicant's claim as a blueprint to piece together the cited references to construct an obviousness rejection. This type of hindsight obviousness analysis has been condemned by the Federal Circuit Court of Appeals as an improper test of patentability.

Finally, even if the cited references could be combined as suggested by the Examiner, they do not render the claims obvious. In particular, any combination of Kendrick et al., Bajpal et al. and/or WO 89/00606 does not put one of skill in the art in possession of the claimed invention. As the Examiner has stated, there are differences between the claimed invention and the references. Indeed, none of the reference discloses obtaining a

microfloral biomass having cell aggregate sizes of less than about 150 microns in diameter and the Examiner has failed to provide any reasoning by which one skilled in the art would attempt to obtain the specific microfloral biomass sizes of less than 150 microns. Accordingly, Applicant respectfully requests the Examiner withdraw the rejection of Claims 14-20 under 35 U.S.C. § 103.

It is believed that no fees are due with this communication. If any such fees are due, however, then please debit such fees to Deposit Account 19-1970.

In view of the foregoing remarks, Applicant respectfully submits that Claims 14, 16, 18-20 are in condition for allowance and Applicant respectfully requests the same.

Respectfully submitted,

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